DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98 N-0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices

AGENCY: Food and Drug Administration, HHS,

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations governing establishment registration and device listing by domestic distributors. These amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the Federal Register, FDA is publishing a companion proposed rule, under FDA's usual procedures for notice and comment, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws the direct final rule.

DATES: The regulation is effective *(insert date 135 days after date of publication in the* Federal Register). Submit written comments on or before *(insert date 75 days after date of publication in the* Federal Register). If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the Federal Register within *30* days after the comment period on this direct final rule ends. If FDA receives any significant adverse comment, FDA intends to withdraw this final rule by publication of a document in the Federal Register within 30 days after the comment period ends. These provisions of FDAMA became effective on February 19, 1998.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Walter W. Morgenstern, Center for Devices and Radiological Health (HFZ–305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20857, 301–594–4699.

SUPPLEMENTARY INFORMATION:

L Background

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105–1 15). Section 213(b) of FDAMA made the following changes to section 510(g) of the act (21 U.S.C. 360(g)) regarding domestic distributor registration and 'device listing:

1. FDAMA amended section 510(g) of the act to add a new paragraph (g)(4) to provide that the registration and listing requirements of section 510 of the act do not apply to distributors who act as "wholesale distributor, " and who do not manufacture, repackage, process, or relabel a device.

2. FDAMA also added a definition of "wholesale distributor" to section 510(g) of the act. A "wholesale distributor" is defined as "any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user. "

Section 213 of FDAMA became effective on February 19, 1998, and FDA is implementing the statute as of that date. FDA is issuing this direct final rule to amend certain existing regulations to conform to amendments made by FDAMA to section 510(g) of the act.

IL Amendment Highlights

Section 807.3 (21 CFR 807.3) has been amended to incorporate the new definitions of distributor and wholesale distributor provided in amended section 510(g) of the act.

FDA is also amending § 807.3(g) to add a definition for "initial importer, " because ' 'initial importer" is excluded from the definition of wholesale distributor established by FDAMA.

Sections 807.20 and 807.22 (21 CFR 807.20 and 807.22) have been amended to implement the changes made by FDAMA to section 510(g) of the act, These amendments to 21CFR part 807 exempt distributors of domestic or imported devices from the requirement of establishment registration and device listing. Section 807.20 is further amended to clarify that initial importers of devices continue to be subject to registration and listing.

Sections 807.3, 807.20, and 807.22 have been amended to conform the activities requiring registration with the changes made by FDAMA. Prior to FDAMA, all distributors were required to register and list. Amended section 510(g) of the act exempts wholesale distributors from registration and listing and defines a "wholesale distributor" as any person, other than the manufacturer or initial importer, who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user. The amendments to $$807.3, 807.20, and 807.22 reflect the changes made by FDAMA.

III. Rulemaking Action

In the Federal Register of November 21, 1997 (62 FR 62466), FDA described when and how it will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as making noncontroversial amendments to an existing regulation. The rule incorporates amendments to section 510(g) of the act made by FDAMA and FDA anticipates no significant adverse comment. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing, elsewhere in this issue of the Federal Register, a companion proposed rule to amend certain existing regulations governing establishment registration and device listing by domestic distributors. The companion proposed rule is substantively identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment, The comment period for the direct final rule runs

concurrently with the comment period of the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule of (*insert date* 75 *days after date of publication in the* Federal Register). If the agency receives any significant adverse comment, FDA intends to withdraw this final rule by publication of a document in the Federal Register within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the Administrative Procedure Act (5 U.S.C. 552 *et seq.).* If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation document in the Federal Register within 30 days after the comment period ends. FDA intends to make the direct final rule effective (*insert date 135 days after date of publication in the* Federal Register).

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impact of this direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601 –6 12) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104--4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this direct final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule codifies applicable statutory requirements imposed by FDAMA. Because the rule exempts certain distributors from registration and device listing, it may permit more small competitors to enter the marketplace. The agency certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities. This direct final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

VI. Paperwork Reduction Act of 1995

This direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 –3520) is not required.

VII. Submission of Comments

Interested persons may, on or before *(insert date 75 days after date of publication in the* Federal Register), submit to the Dockets Management Branch (address above) written comments regarding this rule. This comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered comments regarding the proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 807 is amended as follows:

1. The part heading for part 807 is revised to read as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

2. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U. S. C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

3. Section 807.3 is amended by revising paragraphs (d)(2) and (g), and by adding paragraph (s) to read as follows:

§ 807.3 Definitions.

* * * * *

(d) * * *

(2) Initial importation of devices manufactured in foreign establishments; or

* * * * *

(g) Initial importer means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

* * * * *

(s) Wholesale distributor means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

4. Section 807.20 is amended by revising paragraph (a)(4), by redesignating paragraph (d) as paragraph (c) and paragraph (c) as paragraph (d), respective] y, and by adding paragraph (c)(3) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) * * *

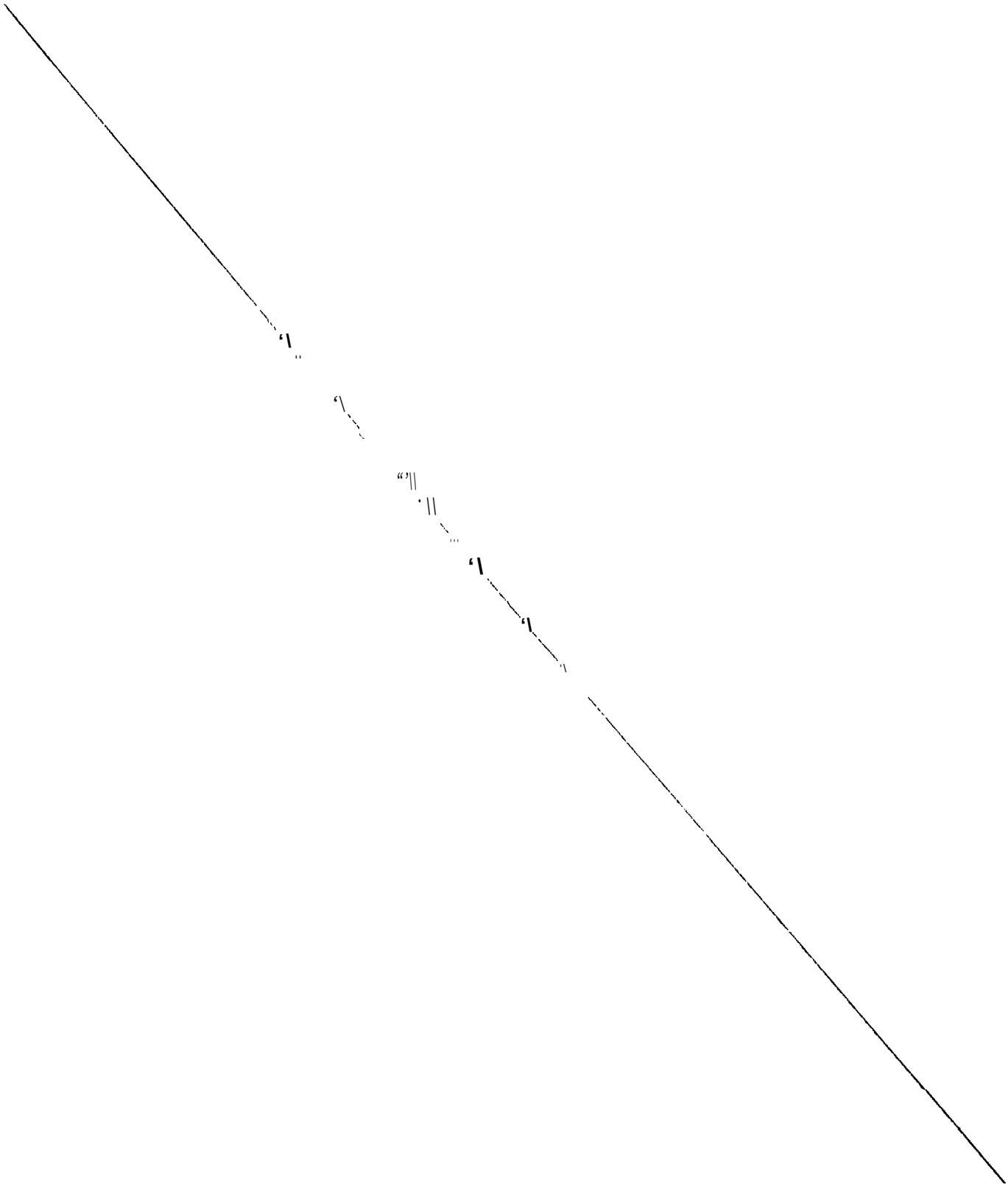
(4) Acts as an initial importer;

* * * * *

(C) * * *

(3) Acts as a wholesale distributor, as defined in § 807.3(s), and who does not manufacture, repackage, process, or relabel a device.

* * * * *



§ 807.22 [Amended]

5. Section 807.22 *How and where to register establishments and list devices is* amended in paragraph (c) by removing the words ‘ ‘distributor” and ‘ ‘distributors” each time they appear and by adding in their place the words “initial importer” and ‘ ‘initial importers”, respectively.

Dated: July 15, 1998

William B. Schultz)
Deputy Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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